IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY, Plaintiff, v. TEVA PARENTERAL MEDICINES, INC., APP PHARMACEUTICALS, LLC, PLIVA HRVATSKA D.O.O., TEVA PHARMACEUTICALS USA, INC., and BARR LABORATORIES, INC., Defendants.	)))))))))	CASE NO. 1:10-CV-1376-TWP-DKL

APP PHARMACEUTICALS, LLC's
ANSWER AND AFFIRMATIVE DEFENSES

Defendant APP Pharmaceuticals, LLC hereby answers the Complaint dated July 15, 2011 ("the Complaint"), filed by Eli Lilly and Company ("Plaintiff") as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the filing by Defendant APP Pharmaceuticals, LLC ("APP") of an Abbreviated New Drug Applications ("ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell generic versions of ALIMTA® prior to the expiration of U.S. Patent No. 7,772,209.

RESPONSE: APP admits that the Complaint purports to state an action that arises under the patent laws of the United States, Title 35, United States Code. APP further admits that it submitted an ANDA and an amendment to that ANDA to the U.S. Food and Drug Administration ("FDA") under the provisions of 21 U.S.C. § 355(b) seeking approval to manufacture and sell generic versions of ALIMTA®, prior to the expiration of U.S. Patent No. 7,772,209 ("the '209 patent"). To the extent that paragraph 1 states conclusions of law, no response is required from APP. APP denies the remaining allegations in paragraph 1.

PARTIES

2. Lilly is a corporation organized and existing under the laws of the State of Indiana, having its corporate offices and principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285.

RESPONSE: Upon information and belief, APP admits the allegations in paragraph 2 of the Complaint.

3. Upon information and belief, defendant APP is a limited liability company organized and existing under the laws of the State of Delaware, having its principal place of business at 1501 East Woodfield Road, Suite 300 East, Schaumburg, Illinois 60173-5837.

RESPONSE: APP admits the allegations in paragraph 3 of the Complaint.

JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

RESPONSE: APP admits the allegations in paragraph 4 of the Complaint.

5. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

RESPONSE: For purposes of this case only, APP admits that venue with respect to APP is proper in this judicial district. APP denies the remaining allegations in paragraph 5 of the Complaint.

6. Upon information and belief, APP is subject to personal jurisdiction in this District because, among other things, APP markets, sells, and distributes generic drugs throughout the United States, including within the State of Indiana and the Southern District of Indiana. Upon information and belief, APP has engaged in and maintained systematic and continuous business contacts within the State of Indiana and the Southern District of Indiana, and has purposefully availed itself of the benefits and protections of the laws of Indiana.

RESPONSE: APP admits that APP markets, sells, and distributes generic drugs throughout the United States, including within the State of Indiana and the Southern District of Indiana. To the extent that paragraph 6 states conclusions of law, no response is required from APP. APP denies the remaining allegations in paragraph 6 of the Complaint.

7. Upon information and belief, and consistent with its practice with respect to other generic products, following any FDA approval of APP's ANDA No. 90-384 for a generic version of ALIMTA®, APP will market, distribute, and sell its generic product throughout the United States and within Indiana and the Southern District of Indiana, and knows that Lilly will be injured by such actions in Indiana and the Southern District of Indiana. Upon information and belief, following any FDA approval of ANDA No. 90-384, APP knows and intends that its generic product will be marketed, distributed, and sold in the United States and within the State of Indiana and the Southern District of Indiana, and knows that Lilly will be injured by such actions in Indiana and the Southern District of Indiana.

RESPONSE: APP is without information sufficient to admit or deny that APP will market, distribute or sell its generic products following any FDA approval of ANDA No. 90-384 and therefore denies the same. APP denies the remaining allegations of paragraph 7.

BACKGROUND

8. ALIMTA® is a chemotherapy drug used for the treatment of various types of cancer. ALIMTA® is indicated (in combination with cisplatin) (a) for the treatment of patients with malignant pleural mesothelioma, or (b) for the initial treatment of locally advanced or metastatic nonsquamous non-small cell lung cancer. ALIMTA® also is indicated as a single-agent for the treatment of patients with locally advanced or metastatic nonsquamous non-small cell lung cancer after prior chemotherapy. ALIMTA® also is indicated for maintenance treatment of patients with locally advanced or metastatic-nonsquamous non-small-cell lung

cancer whose disease has not progressed after four cycles of platinum-based first-line chemotherapy.

RESPONSE: APP admits that ALIMTA® is currently indicated (1) in combination with cisplatin therapy for the initial treatment of patients with locally advanced or metastatic nonsquamous non-small cell lung cancer; (2) for the maintenance treatment of patients with locally advanced or metastatic nonsquamous non-small cell lung cancer whose disease has not progressed after four cycles of platinum-based first-line chemotherapy; (3) as a single-agent for the treatment of patients with locally advanced or metastatic nonsquamous non-small cell lung cancer after prior chemotherapy; and (4) in combination with cisplatin for the treatment of patients with malignant pleural mesothelioma whose disease is unresectable or who are otherwise not candidates for curative surgery. APP is without sufficient information to admit or deny the remaining allegations in paragraph 8 and therefore denies the same.

9. Lilly sells ALIMTA® in the United States pursuant to a New Drug Application that has been approved by the FDA.

RESPONSE: APP admits the allegations in paragraph 9.

10. United States Patent No. 7,772,209 ("the '209 patent"), entitled "Novel Antifolate Combination Therapies", was duly and legally issued on August 10, 2010. The '209 patent is attached as Exhibit A hereto.

RESPONSE: APP admits that, on its face, the '209 patent is entitled "Antifolate Combination Therapies," and shows an issue date of August 10, 2010. APP admits that what appears to be a true and correct copy of the '209 patent is attached to the Complaint as Exhibit A. APP denies the remaining allegations in paragraph 10 of the Complaint.

11. Lilly is the assignee of the '209 patent. As set forth in greater detail in the '209 patent, one or more claims of the '209 patent, incorporated by reference herein, cover a method of administering pemetrexed disodium to a patient in need thereof that also involves administration of folic acid and vitamin B_{12}.

RESPONSE: APP admits that the face of the '209 patent states that it is assigned to Eli Lilly and Company. APP states that to the extent the remaining allegations of paragraph 11 call for a legal conclusion, no response is required. APP denies the remaining allegations in paragraph 11 of the Complaint.

12. An actual case or controversy exists between Lilly and APP with respect to infringement of the '209 patent.

RESPONSE: To the extent that paragraph 12 states conclusions of law, no response is required from APP. APP denies the remaining allegations in paragraph 12 of the Complaint.

COUNT I
(Patent Infringement - 500 mg)

13. Lilly incorporates each of the preceding paragraphs as if fully set forth herein.

RESPONSE: APP incorporates each of the preceding paragraphs as if fully set forth herein.

14. By letters dated June 10, 2008 ("APP's 2008 Notice Letter") and June 2, 2011 ("APP's 500 mg Notice Letter"), APP notified Lilly that it had submitted to the FDA ANDA No. 90-384 for APP's Pemetrexed Disodium Injectable, Eq. 500 mg Base/Vial product.

RESPONSE: APP admits that by letters dated June 10, 2008 and June 2, 2011, APP notified Plaintiff that APP had submitted to the FDA ANDA No. 90-384 for APP's Pemetrexed Disodium for Injection, Eq. 500 mg Base/Vial product.

15. APP's 500 mg ANDA Product is a generic version of ALIMTA®.

RESPONSE: APP admits that APP's proposed 500 mg ANDA Product is a generic version of ALIMTA®.

16. The purpose of ANDA No. 90-384 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of APP's 500 mg ANDA Product prior to the expiration of the '209 patent.

RESPONSE: APP admits that APP submitted ANDA No. 90-384 to the FDA under the provisions of 21 U.S.C. § 355(b) seeking approval to engage in the commercial manufacture, use, offer for sale, and/or sale of APP's proposed 500 mg ANDA Product prior to the expiration of the '209 patent. APP is without sufficient information to admit or deny the remaining allegations in paragraph 16 of the Complaint and therefore denies the same.

17. In APP's 2008 Notice Letter and APP's 500 mg Notice Letter, APP notified Lilly that APP's 500 mg ANDA Product contains pemetrexed disodium.

RESPONSE: APP admits that in APP's 2008 Notice Letter and APP's 500 mg Notice Letter, APP notified Lilly that APP's proposed 500 mg ANDA Product contains pemetrexed disodium.

18. Upon information and belief, the use of APP's 500 mg ANDA Product in accordance with APP's proposed labeling for APP's 500 mg ANDA Product involves administration of folic acid and vitamin B_{12}.

RESPONSE: The proposed labeling for APP's 500 mg ANDA Product has not been finalized and therefore APP is without information sufficient to admit or deny the allegations in paragraph 18 of the Complaint.

19. Upon information and belief, the use of APP's 500 mg ANDA Product in accordance with and as directed by APP's proposed labeling for that product will infringe one or more claims of the '209 patent.

RESPONSE: APP states that to the extent the allegations of paragraph 19 call for a legal conclusion, no response is required. APP denies the remaining allegations in paragraph 19 of the Complaint.

20. APP's submission of ANDA No. 90-384 is for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of APP's 500 mg ANDA Product prior to the expiration of the '209 patent.

RESPONSE: APP admits that a purpose of obtaining approval is to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of APP's proposed 500 mg ANDA Product prior to the expiration of the '209 patent. APP denies the remaining allegations in paragraph 20 of the Complaint.

21. Upon information and belief, APP intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of APP's 500 mg ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 90-384, *i.e.,* prior to the expiration of the '209 patent.

RESPONSE: APP is without information sufficient to admit or deny that APP will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of APP's proposed 500 mg ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 90-384 and therefore denies the same. APP denies the remaining allegations in paragraph 21 of the Complaint.

22. Upon information and belief, APP has knowledge of the claims of the '209 patent. Notwithstanding this knowledge, APP has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of APP's 500 mg ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 90-384.

RESPONSE: APP admits that APP has knowledge of the claims of the '209 patent. APP is without information sufficient to admit or deny that APP will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of APP's proposed 500 mg ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 90-384 and therefore denies the same. APP denies the remaining allegations in paragraph 22 of the Complaint.

23. Upon information and belief, APP plans and intends to, and will, actively induce infringement of the '209 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

RESPONSE: APP denies the allegations in paragraph 23 of the Complaint.

24. Upon information and belief, APP knows that APP's 500 mg ANDA Product is especially made or adapted for use in infringing the '209 patent, and that APP's 500 mg ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, APP plans and intends to, and will, contribute to infringement of the '209 patent immediately and imminently upon approval of ANDA No. 90-384.

RESPONSE: APP denies the allegations in paragraph 24 of the Complaint.

25. The foregoing actions by APP constitute and/or will constitute infringement of the '209 patent, active inducement of infringement of the '209 patent, and contribution to the infringement by others of the '209 patent.

RESPONSE: APP denies the allegations in paragraph 25 of the Complaint.

26. Upon information and belief, APP is without a reasonable basis for believing that it will not be liable for infringing the '209 patent, actively inducing infringement of the '209 patent, and/or contributing to the infringement by others of the '209 patent.

RESPONSE: APP denies the allegations in paragraph 26 of the Complaint.

27. Unless APP is enjoined from infringing the '209 patent, actively inducing infringement of the '209 patent, and contributing to the infringement by others of the '209 patent, Lilly will suffer irreparable injury. Lilly has no adequate remedy at law.

RESPONSE: APP denies the allegations in paragraph 27 of the Complaint.

COUNT II
(Patent Infringement - 100 mg)

28. Lilly incorporates each of the preceding paragraphs as if fully set forth herein.

RESPONSE: APP incorporates each of the preceding paragraphs as if fully set forth herein.

29. By a letter dated June 2, 2011 ("APP's 100 mg Notice Letter"), APP notified Lilly that it had submitted to the FDA a Supplement to ANDA No. 90-384 for APP's Pemetrexed Disodium Injectable, Eq. 100 mg Base/Vial product.

RESPONSE: APP admits that by a letter dated June 2, 2011, APP notified Plaintiff that APP had submitted to the FDA a supplement to ANDA No. 90-384 for APP's Pemetrexed Disodium for Injection, Eq. 100 mg Base/Vial product.

30. APP's 100 mg ANDA Product is a generic version of ALIMTA®.

RESPONSE: APP admits that APP's proposed 100 mg ANDA Product is a generic version of ALIMTA®.

31. The purpose of ANDA No. 90-384 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of APP's 100 mg ANDA Product prior to the expiration of the '209 patent.

RESPONSE: APP admits that APP submitted a supplement to ANDA No. 90-384 to the FDA under the provisions of 21 U.S.C. § 355(b) seeking approval to engage in the commercial manufacture, use, offer for sale, and/or sale of APP's proposed 100 mg ANDA Product prior to the expiration of the '209 patent. APP is without sufficient information to admit or deny the remaining allegations in paragraph 31 of the Complaint and therefore denies the same.

32. In APP's 100 mg Notice Letter, APP notified Lilly that APP's 100 mg ANDA Product contains pemetrexed disodium.

RESPONSE: APP admits that in APP's 100 mg Notice Letter, APP notified Lilly that APP's proposed 100 mg ANDA Product contains pemetrexed disodium.

33. Upon information and belief, the use of APP's 100 mg ANDA Product in accordance with APP's proposed labeling for APP's 100 mg ANDA Product involves administration of folic acid and vitamin B_{12}.

RESPONSE: The proposed labeling for APP's 100 mg ANDA Product has not been finalized and therefore APP is without information sufficient to admit or deny the allegations in paragraph 33 of the Complaint.

34. Upon information and belief, the use of APP's 100 mg ANDA Product in accordance with and as directed by APP's proposed labeling for that product will infringe one or more claims of the '209 patent.

RESPONSE: APP states that to the extent the allegations of paragraph 34 call for a legal conclusion, no response is required. APP denies the remaining allegations in paragraph 34 of the Complaint.

35. APP's submission of ANDA No. 90-384 is for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of APP's 100 mg ANDA Product prior to the expiration of the '209 patent.

RESPONSE: APP admits that a purpose of obtaining approval is to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of APP's proposed 100 mg ANDA Product prior to the expiration of the '209 patent. APP denies the remaining allegations in paragraph 35 of the Complaint.

36. Upon information and belief, APP intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of APP's 100 mg ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 90-384, *i.e.,* prior to the expiration of the '209 patent.

RESPONSE: APP is without information sufficient to admit or deny that APP will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of APP's proposed 100 mg ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 90-384 and therefore denies the same. APP denies the remaining allegations in paragraph 36 of the Complaint.

37. Upon information and belief, APP has knowledge of the claims of the '209 patent. Notwithstanding this knowledge, APP has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of APP's 100 mg ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 90-384.

RESPONSE: APP admits that APP has knowledge of the claims of the '209 patent. APP is without information sufficient to admit or deny that APP will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of APP's proposed 100 mg ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 90-384 and therefore denies the same. APP denies the remaining allegations in paragraph 37 of the Complaint.

38. Upon information and belief, APP plans and intends to, and will, actively induce infringement of the '209 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

RESPONSE: APP denies the allegations in paragraph 38 of the Complaint.

39. Upon information and belief, APP knows that APP's 100 mg ANDA Product is especially made or adapted for use in infringing the '209 patent, and that APP's 100 mg ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, APP plans and intends to, and will, contribute to infringement of the '209 patent immediately and imminently upon approval of ANDA No. 90-384.

RESPONSE: APP denies the allegations in paragraph 39 of the Complaint.

40. The foregoing actions by APP constitute and/or will constitute infringement of the '209 patent, active inducement of infringement of the '209 patent, and contribution to the infringement by others of the '209 patent.

RESPONSE: APP denies the allegations in paragraph 40 of the Complaint.

41. Upon information and belief, APP is without a reasonable basis for believing that it will not be liable for infringing the '209 patent, actively inducing infringement of the '209 patent, and/or contributing to the infringement by others of the '209 patent.

RESPONSE: APP denies the allegations in paragraph 41 of the Complaint.

42. Unless APP is enjoined from infringing the '209 patent, actively inducing infringement of the '209 patent, and contributing to the infringement by others of the '209 patent, Lilly will suffer irreparable injury. Lilly has no adequate remedy at law.

RESPONSE: APP denies the allegations in paragraph 42 of the Complaint.

APP denies each and every allegation contained in the Complaint not expressly admitted above. APP denies that Plaintiff is entitled to the judgment and relief prayed for in paragraphs (a) through (j) of the Complaint.

FIRST AFFIRMATIVE DEFENSE

The manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Pemetrexed Disodium for Injection that is the subject of ANDA No. 90-384, and any supplement thereto, does not and will not infringe valid and enforceable claims of the '209 patent.

SECOND AFFIRMATIVE DEFENSE

The claims of the '209 patent are invalid under 35 U.S.C. §§ 101 *et seq.* and for obviousness-type double patenting.

APP reserves the right to raise further additional defenses as may be available upon the facts to be developed and under applicable substantive law.

WHEREFORE, APP prays that this Court:

A. Enter an order dismissing the Complaint, with prejudice, and denying Plaintiff the relief requested in the Complaint and any relief whatsoever;

B. Deny Plaintiff any award of damages, costs, or fees;

C. Declare this case exceptional and award APP reasonable attorneys fees;

D. Award APP their costs; and

E. Grant such other and further relief as this Court may deem just.

Dated: September 19, 2011

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on September 19, 2011, a copy of the foregoing document was filed electronically. Notice of this filing will be sent to the following parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system:

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